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April 10, 2000

David W. Feigal, M.D., M.P.H.
Director, Center for Devices and Radiological Health
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061, (HFA-305)
Rockville, MD 20852

Re: Docket # 00D-0053 -Reprocessing and Reuse of Single-Use Devices: Risk Prioritization Scheme; and Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.

Dear Dr. Feigal:

Tyco Healthcare Group, LP (referred to as Tyco Healthcare) welcomes the opportunity to submit the following comments for your consideration in response to the FDA's February 8, 2000 Guidance Document entitled -- "Reprocessing and Reuse of Single-Use Devices: Risk Prioritization Scheme; and Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Docket # 00D-0053).

INTRODUCTION

Divisions of Tyco Healthcare design, manufacture and distribute sterile single-use medical devices in many healthcare categories including wound care, laparoscopic instrumentation, electrosurgcial accessories, stapling devices, hypodermic needles and syringes, cardiovascular surgical and access

catheters, and suturing products, to name just a few. Our comments represent the opinion of an original equipment manufacturer of Class I, II and III reusable and single-use devices. As a group, our products are sold globally under several brand names, including Kendall, Sherwood Medical, U.S. Surgical, and Valleylab.

The reuse of single use items has been a topic of concern for many years. It is a practice we have watched escalate over the past several years and we welcome the opportunity to submit these comments for the Agency's consideration. To ensure mutual understanding of the issues raised in this correspondence, our comments closely adhere to FDA's *Definitions of Terms* found in Appendix A, page 18, of the FDA's Guidance for Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, dated 2/8/00.

FDA's proposal to enforce the law with respect to the growing practice of reprocessing devices labeled for "Single Use Only" is warranted as the practice of reprocessing of single-use devices is in direct violation of existing FDA regulations. Enforcement of existing laws is necessary to protect public health and public confidence. We strongly support the Agency as it takes steps to implement a regulatory structure that will hold reprocessors to the same stringent regulatory standards[1] that original equipment manufacturers must fulfill.

While we appreciate the progress the Agency has made with the latest draft of the Guidance Documents for Reuse of SUDs, we have additional concerns that warrant consideration. The following five issues are presented for consideration before the Agency releases its final document.

[1] These requirements include registration & listing, medical device reporting, device tracking, correction & removal reports, quality system requirement, premarket requirements, and labeling.

CONSIDERATION #1

510(k) Exempt Single-Use Devices Should Not Be Exempt When Reprocessed

Under the proposed plan, single-use devices exempt from 510(k) premarket requirements would also be exempt as reprocessed devices. Implementation of this proposal would allow reprocessors to operate outside the intent of the original device exemption. The original exemption was based upon the description and intended use of a specific device. The new intended use of the device (i.e. reusable) needs to be considered independent of the exemption status. Single-use devices that are currently exempt from 510(k) requirements share commonalties that when reprocessed would be lost:

- Exempt single-use devices are manufactured with homogeneous materials in standard and consistently controlled production environments. The current proposal would allow the exempt single-use device to be reprocessed with unspecified materials (blood, body fluids, tissue, etc.), in multiple environments (hospital central supply and/or reprocessor facility), coupled with a variety of reprocessing methodologies.
- The exempt single-use device has mechanical functions that are straightforward, simple and easily understood. The original single-use device is granted 510(k) exemption based upon comparable functionality of the device in accordance with its intended single use.
- The design and manufacturing of the original single-use device does not take into consideration the design features needed to withstand the stressors associated with re-sterilization, post-use cleaning, decontamination, the potential as a vector for biological contamination, or the effect of reprocessing on the longevity of the device's functionality.

The FDA Office of Device Evaluation has recognized this distinction in it's own guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device" which states

"common labeling changes that impact intended use and would usually require submission of a 510(k) [include] reuse of devices previously labeled single use only."[2]

In addition, the FDA's device classification database contains inconsistencies in product code assignment which if implemented to categorize reused devices will result in some devices being inappropriately categorized as class I, 510(k) exempt. For example, the Auto Suture LDS* device is a gas-powered device for ligation and division of vasculature and other small tubular structures. FDA's database categorizes this device as a "Nasal Saw Blade"[3] and places it in product code *KBS*, a product code for devices listed under CFR 874.4420--"Ear, nose, and throat manual surgical instruments"[4], which under the current guidance document would make this device exempt from 510(k) requirements. A more appropriate product category for the LDS* device would be 79GWD listed under CFR 878.4750. Similarly, the list of frequently reprocessed SUDs lists the regulation for electrosurgical electrodes/handles/pencils as CFR 878.4800. The correct regulation is CFR 878.4400.

Finally, a review of the list of frequently reprocessed devices included in Appendix B of the Draft Guidance Document demonstrates most effectively why blanket exemption from premarket clearance should not be granted for reprocessed versions of exempt single-use devices. The list includes twenty-five (25) product categories that are currently 510(k) exempt. Of these, FDA estimated reprocessing risks and concluded that twelve (12) products posed "Low" risk, nine (9) posed "Moderate" risk, and four (4) posed "High" risk to patients! If reprocessing a product poses known risk to patients, how can the Agency conclude that such reprocessing be exempt from premarket clearance? This current draft guidance is inconsistent with the FDA's premarket notification exemption rules.

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[2] Deciding when to submit a 510(k) for a change to an existing device, Memorandum No. K97-1, *Center for Devices and Radiological Health, Office of Device Evaluation*, Jan 10, 1997, p. 10.
[3] 510(k) K810188, Auto Suture Gas Powered Disposable LDS Stapler.
[4] Code of Federal Regulations, Title 21, Volume 8, Part 874.4420, April 1, 1999.

In view of these significant concerns, we request that the Agency reconsider the safety implications of 510(k) exempt single-use devices being exempt when reprocessed. We believe all reused single-use devices, regardless of original device exemption, should be subject to premarket 510(k) or PMA requirements.

CONSIDERATION #2:

The Agency Should Enforce Premarket Clearance Requirements As Fast as Possible

Any phase-in of premarket clearance requirements continues to compromise the Agency's responsibility to protect the public. As an original device manufacturer, Tyco Healthcare is restricted from selling any device that requires a premarket 510(k) or PMA until that device receives Agency clearance for safe patient use. As recently as September 18, 1999, the Agency required U. S. Surgical to submit premarket notification (K983293) for the Auto Suture* Laparoscope Device, a refurbished scope originally manufactured by Imagyn Medical, Inc. Before U. S. Surgical could market this product, the Agency required evidence that the reprocessing procedure did not significantly change the laparoscope's performance, safety specifications and/or intended use. Reprocessors of single-use devices should be held to these same requirements as soon as possible to ensure the protection of the public health and to eliminate the disparity between the FDA's treatment of the reprocessors and its treatment of the original equipment manufacturers.

It is our understanding that the FDA believes that some form of phase-in is a necessary transitional mechanism to ensure proper handling of the expected flood of premarket applications, taking into account available agency resources. We believe FDA is overestimating the number of applications it will receive. However, we urge the FDA to adhere to the timelines laid out in the Proposed Guidance Document. Two years is more than enough time to phase in the premarket clearance for reprocessed devices, and the agency must resist any efforts to extend the proposed deadlines.

CONSIDERATION #3

The Agency's Proposed Risk Prioritization Scheme Should Be Limited to the Phase-In Period.

Tyco Healthcare appreciates the fact that the February Draft Guidance Document limits the use of the proposed Risk Prioritization Scheme solely to determining the dates during the proposed premarket clearance phase-in period when applications will be due and their review completed. Earlier proposals to create a separate device classification system for reprocessed devices lacked both a legal foundation and substantive merit.

While the application of the Risk Prioritization Scheme has been limited, the Scheme itself has deficiencies. Any effort to use the Scheme for any purpose other than timing during the phase-in period would produce inconsistent results potentially endangering the public health.

Application of the proposed Risk Prioritization Scheme results in numerous product-specific inconsistencies that could compromise patient safety. For example, the risk designation for U.S. Surgical's laparoscopic dissector is low; while the risk designation for U.S. Surgical's laparoscopic grasper under the proposed scheme is high. However, when both of these devices are compared, it is evident that they should be treated in the same manner:

- Both are classified as "critical" devices.
- Both are of virtually identical design (long, narrow lumens, inaccessible surfaces, etc.) that impedes thorough cleaning and adequate re-sterilization/disinfection (see Exhibit A).
- Both are labeled under the same product code (HET) and CFR code (884.1720).

Another product-specific example that illustrates the flawed nature of the proposed Risk Prioritization Scheme regards trocars used in minimally invasive surgery. U. S. Surgical

manufactures both disposable and reusable trocar lines, specifically the Versaport* V2 and Versaport* RT, respectively. Both products are listed in Product Code GCJ, labeled as Class II devices and are assigned "moderate" risk despite distinct differences in these products. Exhibits B and C illustrate the key differences between these products:

- The Versaport* V2 is a single-use product that cannot be taken apart without destroying the instrument. Its obturator contains a retractable knife blade within a parabolic entry shield that creates inaccessible surfaces that compromise the ability to adequately clean and resterilize the device.
- The Versaport* RT is a reusable trocar system that can be taken apart. The system is comprised of a reusable titanium cannulae and a single-use obturator and seal. The titanium cannulae provide access to all surfaces for adequate cleaning and re-sterilization. The obturator and seal on the other hand cannot be taken apart, have inaccessible surfaces and cannot be adequately cleaned and re-sterilized.

These devices clearly differ for one reason, one is intended for single-use, while the other is intended for multiple uses, cleanings, and resterilizations. Therefore, the infection risk and inadequate performance risk assigned to these products when reprocessed is not the same and should not be categorized as equivalent.

The proposed Risk Prioritization Scheme also mistakenly assumes that the existence of a reusable device in the same product category as a single-use device lessens the infection risk of that single-use device when reprocessed. This assumption does not take into account that reusable devices are designed with different specifications and materials in order to achieve safety and efficacy for multiple cleaning, re-sterilization, and use. It is plainly incorrect to assume that sterilization/disinfection can be accomplished on a single-use device by using techniques directed by labeling for the "equivalent reusable device". The existence of a reusable product of the same product category is not relevant to the determination of risk.

The flowcharts incorporated as part of the Risk Prioritization Scheme also exhibit significant misunderstandings regarding issues that should be considered in regard to reprocessing:

- Question 5 (Flow Chart l) and Questions 2a and 4 (Flow Chart #2) erroneously assume that the availability of consensus standards, performance tests or guidance documents will lessen the risks associated with reprocessing single-use devices. The key question is whether the reprocessor documents adherence to those standards, performance tests and guidance documents for each single-use device it reprocesses.[5]

- In regard to Flowchart 2, Tyco Healthcare is at a loss to understand why any question other than Question #3 is necessary. That question states: "Does the single-use device contain any materials, coatings or components that may be damaged or altered by a single-use or by reprocessing and/or resterilization in such a way that the performance of the device may be affected?" If the answer is in the affirmative, there is obvious patient risk and rapid, if not immediate, premarket review is called for.

Finally, in written comments presented at the February 10, 2000 Hearing of the House Commerce Subcommittee on Oversight and Investigations, Dr. Feigal stated that the determination of risk contained in the proposed Risk Prioritization Scheme relies on insufficient post-market information.

For the reasons discussed above, we believe this scheme is flawed and urge the FDA to remedy these errors when issuing its final document.

[5] Flowchart 1 and 2, Reprocessing and Reuse of Single-Use Devices: Risk Prioritization Scheme, February 8, 2000, pp.23-24.

CONSIDERATION #4:

Institute a Process for Labeling Reprocessed Single-Use Devices

One important area that the Agency has not targeted for reform is labeling. A very troubling aspect of reprocessed single-use devices is that the patient and physician typically are unaware that reprocessed devices are being used. The American College of Surgeons' response to the Agency's proposal clearly establishes the physician's lack of awareness.[6] This omission contributes to the situation that patients are being subjected to the use of reprocessed devices during medical procedures without informed consent or without any notice whatsoever. In addition, the absence of specific direction from the FDA for new labeling requirements compromises the validity and usefulness of post market information such as adverse event and medical device reporting.

To create consistency in regulatory oversight, we recommend that labeling provisions specified in 21 CFR Part 801 also be required of reprocessors of single-use devices:

- Reprocessors, like an original equipment manufacturer, should be required to provide labeling that is comprehensive, including device precautions, adequate directions for use, etc.
- Labeling of reprocessed single-use devices should clearly disclose that the device has been reprocessed and include identification of the party responsible for reprocessing.[7]
- It is critical that the **actual unit is labeled clearly and permanently** with the name of the reprocessor for the end-user to see. Package labeling, while important, is insufficient given the practicalities of the healthcare environment. For example, in the operating room,

[6] ACS Comments on Legislation and Regulations- Single Use Medical Devices, Letter to Larry D. Spears, Director of FDA's Center for Devices and Radiological Health, December 22, 1999.

[7] Under present conditions, it is typical that the original manufacturer receives a complaint concerning one of its devices that has failed after being subjected to reprocessing, because it is not clear to users who is the responsible entity.

re-used device packaging is typically discarded before the instrument tray is seen by the OR team.

- Reprocessors should be required to permanently affix a unique product identifier to the reprocessed single-use device for the following reasons:
  - This identifier would provide a mechanism for these reprocessed single-use devices to be tracked back to the reprocessor in the event of a complaint, recall, or medical device report.
  - The unique identifier will provide a means to determine how many times a reprocessed single-use device has been used.
  - The unique identifier will also provide HCFA with a methodology to track reused single-use devices for appropriate patient billing.
- To avoid misleading the end-user and misbranding the device, the labeling of the reprocessed single-use device should make no reference to the original equipment manufacturer.[8]

Absent the imposition and enforcement of such label requirements, the post-market surveillance of reprocessed single-use devices will remain flawed. Furthermore, while such FDA labeling requirements would not assure that physicians impart this information to their patients, it would go a long way to establish this as a duty of disclosure that must be weighed by the clinician and institution prior to use of reprocessed devices. It should be without question that FDA's strategy to regulate the practice of re-using single use devices include requirements for clearly disclosing that a single-use device has been reprocessed and identifying the party responsible for reprocessing.

[8] "Among representations in the labeling of a device which renders such device misbranded is a false or misleading representation with respect to another device or a drug or food or cosmetic..." Code of Federal Regulations, Title 21, Volume 8, Part 801.6, April 1, 1999. A collateral consideration is the furtherance of the requirements of intellectual property and commercial law. Under certain circumstances, a person may not lawfully use the trademark of another without permission nor hold out another person's product as one's own without permission. Labeling of reprocessed devices with the identity of the reprocessor furthers adherence to these requirements."

CONSIDERATION #5:

Informed Consent should be obtained when a Single-Use Device is reused.

Ideally, patient informed consent is warranted[9]. It may be that, as stated by Dr. Fiegel at the February 10, 2000 Hearing of the House Commerce Subcommittee on Oversight and Investigations, a general informed consent requirement is an issue that is "outside the Agency's regulatory jurisdiction". If so, then this initiative should be pursued in other forums by the healthcare industry and other concerned parties. Patients and healthcare practitioners have a right to know.

Due in no small part to the reputation the FDA has rightfully earned for its consistent enforcement of the Food, Drug and Cosmetic Act and accompanying regulations, patients and clinicians have the expectation that all marketed devices have been reviewed by the FDA for safety and efficacy. If a device is to be used in a manner so plainly contrary to the expectations of patients and clinicians alike, it would seem in the interest of full and fair disclosure for FDA to exercise the authority it currently has to require the fact that the device has been reprocessed to prominently appear on the device's label.

CONCLUSION

Upon review and consideration of the five issues raised in this correspondence, we would welcome the opportunity to provide additional information to the Agency and engage in an active dialogue with the Agency on any of these issues before a final document is released. As an original device manufacturer, the manufacturing divisions of Tyco Healthcare have an established reputation for providing customers worldwide with high quality, low cost and dependable

[9] "Informed consent" is generally understood as the physician's duty to adequately disclose "material" information needed for a patient to judge the relative amounts of risk that the layman can understand well enough to make a prudent decision for his own welfare. A risk is material: "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk of or cluster of risks including whether or not to forego the proposed therapy." Canterbury v. Spence, 464 F.2d 772 (D.C. Cir., 1972).

products. We encourage the Agency to contact Tyco Healthcare for further information. We commend the Agency on the attention and progress it has made on this issue and we look forward to a final guidance document that will establish clear and equitable review of medical devices before they are allowed on the market for safe use in patient care.

Sincerely,

Kathryn Barry, MPH, MSN, RN
Vice President, Strategic Services

Lawrence T. Gibbons
Vice President, Quality Assurance/Regulatory Affairs

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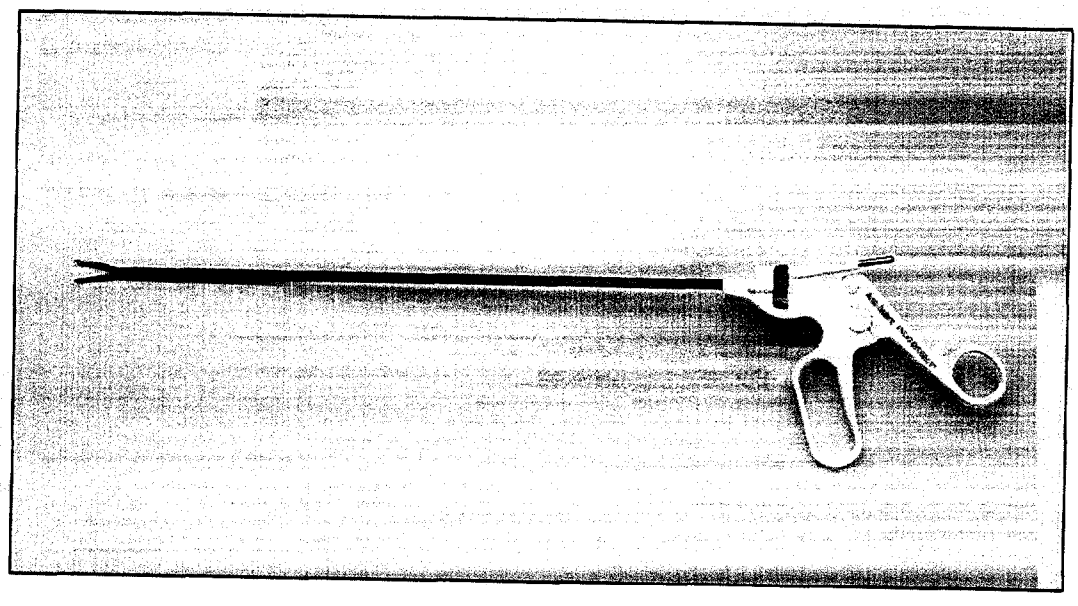
EXHIBIT A

Product Code - HET CFR - 884.1720

AutoSuture ENDODISSECT*
Risk Category - LOW



AutoSuture ENDOGRASP*
Risk Category - HIGH

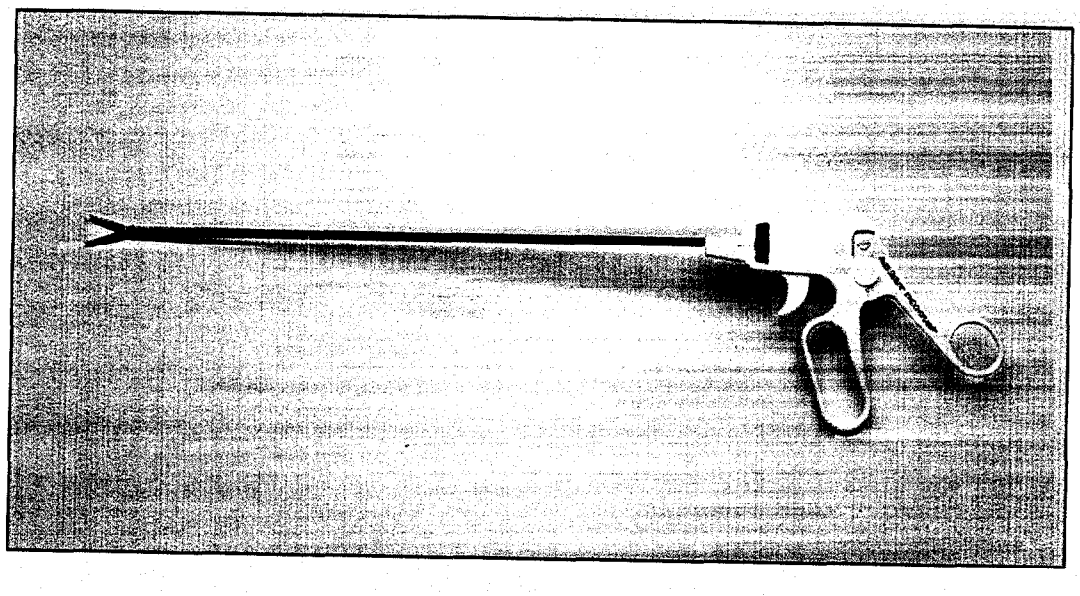


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EXHIBIT B

Product Code - GCJ **CFR - 876.1500**

Risk Category - Moderate

AutoSuture Versaport* V2

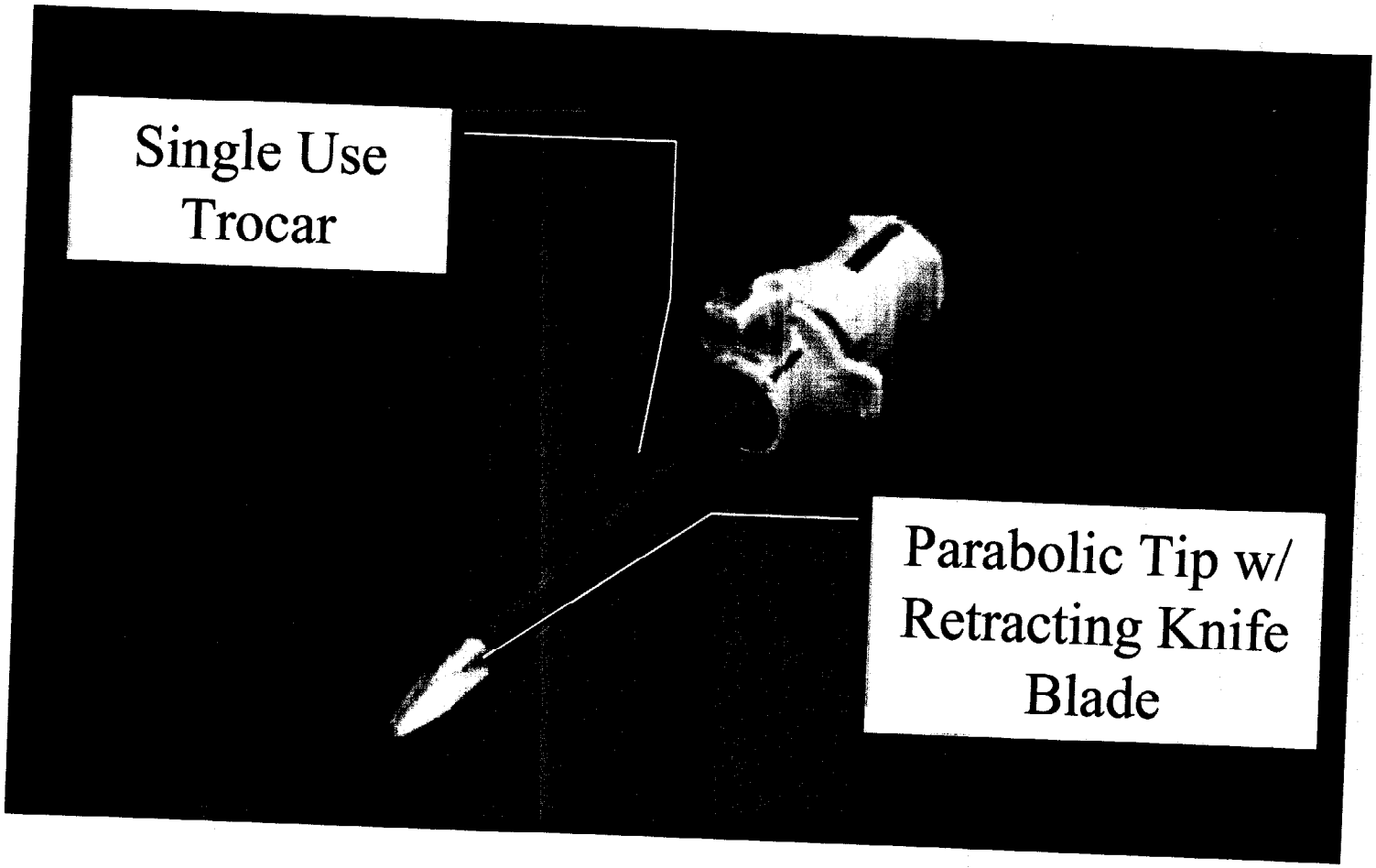

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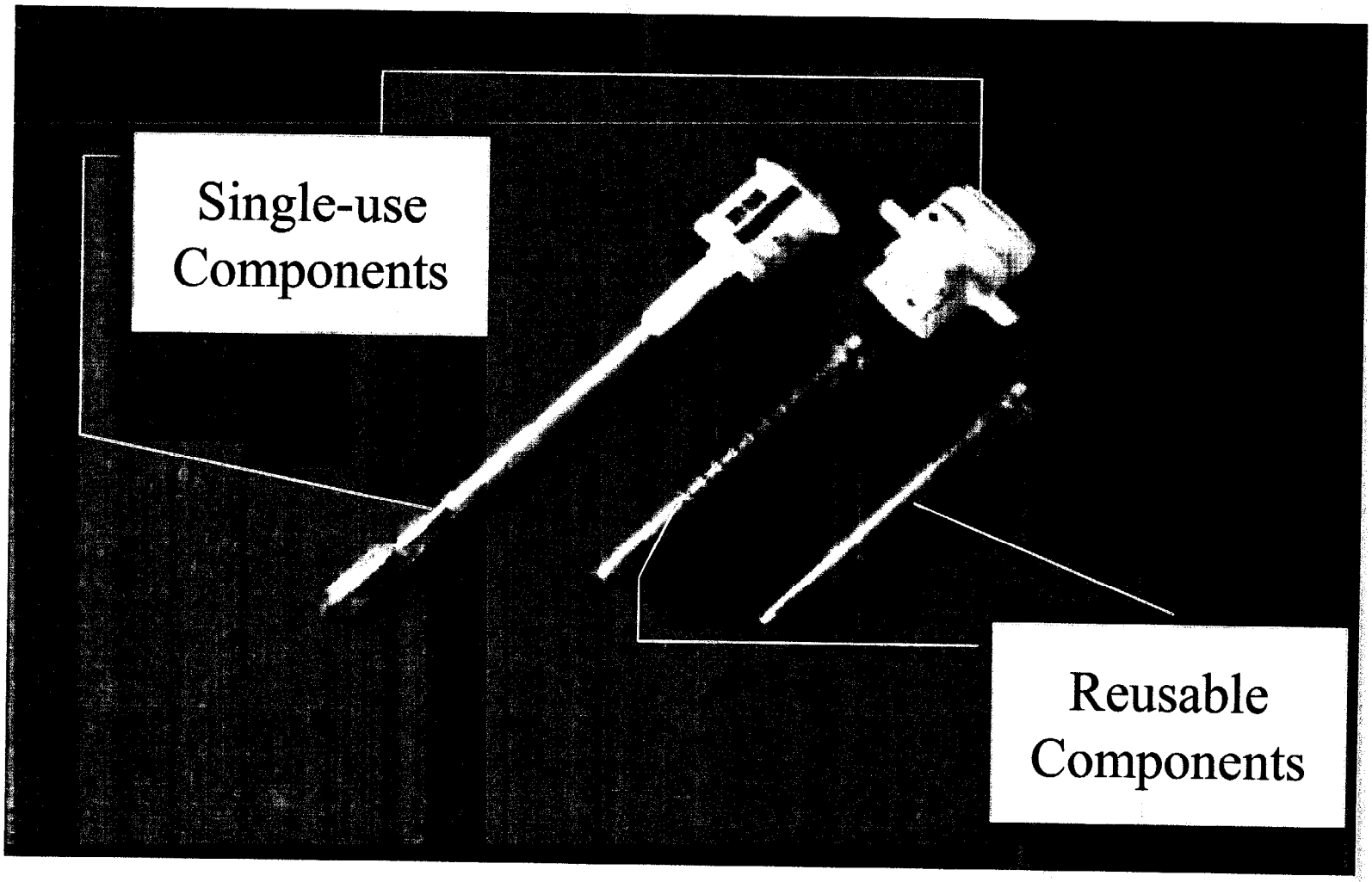
EXHIBIT C

Product Code - GCJ **CFR - 876.1500**

Risk Category - Moderate

AutoSuture Versaport* RT



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